

**REMARKS**

Reconsideration and withdrawal of the objections to and rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-17 are pending. Claims 1, 7-11 and 13-17, the specification and Figures 2A, 2B, 3B, 6-13, 15-23 and 25 are amended without prejudice.

No new matter is added by these amendments.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations in the claims is found throughout the specification.

**II. OBJECTIONS TO THE DRAWINGS**

The drawings were objected to because Figures 7, 9, 11, 13, 17-19, 21, 23, 25 and 26 allegedly contained inaccuracies; Figures 2A and 2B had encircled reference number; lead lines were missing in Figures 6, 8, 10, 12, 16, 20 and 22; and reference number 110 was missing in Figure 3.

Replacement Sheets for Figures 2A, 2B, 3B, 6-13, 15-23 and 25, enclosed herewith, overcome these objections. Consequently, reconsideration and withdrawal of the objections to the drawings are respectfully requested.

### III. OBJECTIONS TO THE SPECIFICATION

The specification was objected to under 37 C.F.R. §§1.58(a) and 1.71(b). The objections are traversed. The amendments to the specification render the rejection moot.

Consequently, reconsideration and withdrawal of the objection to the specification are respectfully requested.

### IV. 35 U.S.C. §112, FIRST PARAGRAPH, REJECTIONS--WRITTEN DESCRIPTION

Claims 1-4 and 7-17 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. The rejection is traversed.

The Examiner expressed concern that the alleged mathematical discrepancies in the specification would lead a skilled artisan to assume that Applicants' did not have possession of the instant invention. Although Applicants disagree, the specification is amended to better clarify the mathematics involved, thereby alleviating the Examiner's concerns. It is asserted that these clarifications do not introduce new matter and are commonly-known mathematical equations falling within the knowledge of a skilled artisan.

Applicants clearly have possession of the instant invention. To this end, the Examiner is respectfully reminded of the state of the law in *In re Herschler*, 591 F. 2d 693, 700 (C.C.P.A. 1979), where the predecessor court to the Federal Circuit explained that:

The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied upon, the specific subject matter later claimed by him; how the specification accomplishes this is not material. The claimed subject matter need not be described *In haec verba* to satisfy the description requirement. It is not necessary that the application describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that appellants invented processes including those limitations.

*In re Herschler*, 591 F. 2d 693, 700 (C.C.P.A. 1979) (internal citations omitted).

Against this background, Applicants believe that the instant specification contains sufficient information to make a skilled artisan appreciate that Applicants had possession of the claimed invention at the time of filing. Therefore, possession of the claimed invention clearly exists.

Consequently, reconsideration and withdrawal of the Section 112, first paragraph, rejection are respectfully requested.

**V. 35 U.S.C. §112, FIRST PARAGRAPH, REJECTIONS—ENABLEMENT**

Claims 7-13 were rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabled. The rejection is traversed.

The amendments to the claims render the rejection moot. Moreover, it is respectfully submitted that undue experimentation is not required to practice the instantly claimed invention. The Examiner is invited to review *In re Wands*, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988), wherein the Federal Circuit stated at 1404 that:

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed[.]

[Citations omitted].

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing the factors summarized in *In re Wands*. These factors include, for example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims; all of which must be taken into account.

Thus, applying *Wands*, the following, *inter alia*, is clear: the quantity of experimentation necessary to practice the invention is low; the amount of guidance in the specification is high; the nature of the invention is not such that "an inordinate amount of experimentation" is required; the relative skill of those in the art is high; the art is predictable; and the breadth of the claims is narrow. Thus, and contrary to the allegations in the Office Action, undue experimentation would not be necessary to practice the instantly claimed invention.

Consequently, reconsideration and withdrawal of the Section 112, first paragraph, rejections for alleged lack of enablement are respectfully requested.

#### **VI. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTIONS**

Claims 7-12, 16 and 17 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is respectfully traversed.

The amendments to the claims, without prejudice, render the rejection moot. Consequently, reconsideration and withdrawal of the Section 112, second paragraph, rejection are respectfully requested.

## **VII. 35 U.S.C. § 102 REJECTIONS**

Claims 1-4, 7-12 and 14-17 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 3,430,849 to Gibson et al. Applicants disagree.

The instant invention is directed to a centrifuge apparatus and process in which the volumetric capacity of the rotor assembly can be varied or changed to accommodate different volumes of product sample to be centrifuged. In addition, the present invention provides for replaceable cores with different fin configurations which can be used in the same centrifuge apparatus to change the volumetric capacity of the rotor assembly to allow scale up or scale down of the product sample to be centrifuged without substantially altering selected separation parameters.

More specifically, the separations utilizing the present invention are both scalable and linear. Scalability is the ability to go from one volume of product to another volume of product without significant changes to the centrifuge protocol. Linearity is the ability for the centrifuge to separate different density materials to yield the same purification results and/or concentration. The present invention provides, therefore, a centrifuge apparatus and process in which the volume of the product sample centrifuged can be scaled up or down while maintaining substantially the same selected separation parameters of the process; a centrifuge apparatus and process in which the volumetric capacity of the rotor assembly of the centrifuge can be varied or changed to accommodate different volumes of product sample to be centrifuged; and replaceable cores of different sizes which can be utilized in the same centrifuge apparatus to change the volumetric capacity of the rotor assembly to allow scale ups or scale downs of product sample to be centrifuged without substantially altering selected separation parameters such as

sedimentation path, residence path and flow dynamics. The Gibson patent does not teach or suggest such an invention.

The Examiner is respectfully reminded that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Against this background, the Section 102 rejection must fail. Gibson relates to large-scale centrifugation. The patent fails to disclose and enable scalable, linear separation. Further, the patent fails to disclose and enable replaceable cores with different fin configurations which can be used in the same centrifuge apparatus to change the volumetric capacity of the rotor assembly to allow scale up or scale down of the product sample to be centrifuged without substantially altering selected separation parameters. More specifically, there is no teaching in the Gibson patent of, for example, a centrifuge apparatus operable at certain predetermined parameters depending upon a product to be separated, having a tank assembly and a rotor assembly, wherein said centrifuge apparatus is adapted to be used with a plurality of rotor assemblies, wherein a first rotor assembly of said plurality of rotor assemblies includes a first core having a first core configuration which is contained within a rotor housing of the first rotor assembly to define a first volume capacity such that the product passing through the first rotor assembly having the first volume capacity during rotation of the first rotor assembly in the

centrifuge apparatus achieves a first particle separation of the product, and a second rotor assembly of said plurality of rotor assemblies includes a second core having a second core configuration which is contained with a rotor housing of the second rotor assembly to define a second volume capacity such that product passing through the second rotor assembly having the second volume capacity during rotation of the second rotor assembly in the centrifuge apparatus achieves a second particle separation of the product which is a linear change with respect to the first particle separation.


Consequently, reconsideration and withdrawal of the Section 102 rejection are believed to be in order and such actions are respectfully requested.

**CONCLUSION**

By this Amendment, claims 1-17 should be allowed; and this application is in condition for allowance. Favorable reconsideration of the application, withdrawal of the rejections and objections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited. The Examiner is invited to contact the undersigned if any issues remain to be resolved.

Respectfully submitted,  
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